REMARKS

Claims 1, 3 and 5-14 and 24-32 are pending. Claims 12-14 are currently withdrawn. Claims 2, 4 and 15-23 were previously cancelled. Claim 1 is amended to correct a typographic issue.

Summary of the Claimed Subject Matter

Claim 1 is directed to a delivery system for a coated medical implant. Specifically, claim 1 recites that the implant retention region of a delivery device has an adhesion resistant treatment to prevent damage to the coating of a releasable implant when it is placed on this region. Thus, there is an adhesion resistant treatment between the surface of the implant and the surface of the delivery device.

Claim Rejections Under 35 U.S.C. 103

Claims 1, 3, 7,11 and 24-32 are rejected under 35 USC 103(a) for being allegedly rendered obvious by U.S. Patent 4,950,227 to Savin et al. ("Savin") in view of U.S. Patent 6,287,285 to Michal et al. ("Michal"). Savin does not disclose all the limitations of claim 1, and Michal does not make up for these deficiencies. Specifically, at the least Savin does not disclose an implant adhesion-resistant treatment on the accessible surface of the delivery device; and a releasable implant having an implant coating on the surface in contact with the accessible surface, wherein the implant adhesion-resistant treatment prevents the implant coating from being stripped from an implant surface.

Savin describes a stent delivery system comprising a balloon 14, a stent 16, and two sleeves 16, 18 for holding the stent on the balloon. However, Savin does not disclose an implant coating on the inner surface of the stent that is in physical communication with the balloon. The Examiner admits that "Savin et al. does not disclose a stent having a first implant coating." Although Savin states that the stent can have a lubricious coating (claim 17), there is no disclosure or teaching of what surface this coating would be on, i.e. whether the coating is on the inner or outer surface. Further, there is no reason provided by the references cited or any other reason provided by the Examiner for placing the implant coating on the inner surface of the stent. Additionally, it is known to put a lubricious coating on the outer surface to assist in reducing the friction during insertion into the body lumen (Michal, col 1, lines 17-21). It would be obvious to

one of ordinary skill in that art that any lubricious coating in Savin would be on the outer surface of the stent. Thus, Savin fails to disclose an implant coating on the inner surface of the stent as recited in claim 1.

Furthermore, Savin fails to disclose an adhesion resistant treatment on the outer surface of the balloon (accessible surface) that is in physical communication with the inner surface of the stent. The Examiner refers to column 4, lines 55-57, however this passage merely states, "a lubricating solution can be provided between the balloon 14 and sleeve 18 and 20 to aid in release of stent 16 from the sleeves." Thus, Savin does not disclose an adhesion resistant coating that is located between the implant and the delivery device, but rather provides that a "lubricating solution" may be between the balloon and the sleeves. The sleeves 18 and 20 are not part of the stent 16, and Savin does not state that there is any coating between the stent and the balloon, or even between the stent and the sleeves. Thus, Savin fails to disclose an adhesion resistant treatment as recited in claim 1.

Furthermore, claim 1 recites that "the implant adhesion-resistant treatment prevents the implant coating from being stripped from an implant surface." Since Savin fails to describe a coating on the inner surface of a stent, there would be no motivation to provide an adhesion resistant coating on the delivery device to preserve a non-existent coating on the inner surface of the stent. Thus, Savin does not disclose all the limitations of claim 1 (and all claims that depend therefrom).

Furthermore, with respect to claims 28-30, in addition to the above arguments, Savin also does not disclose any therapeutic in the lubricating solution or anywhere on the balloon or the stent.

It is noted that the Examiner has added claims 24-32 to this rejection but does discuss any of the limitations of these claims. The Examiner is requested to provide support for this rejection or withdraw the rejection.

Regarding Michal, as discussed above, Savin does not disclose all the limitations of claim 1, and Michal does not cure the deficiencies. Michal describes a therapeutic or lubricious coating for an intracorporeal medical device that allegedly strongly adheres to the surface of the device. The embodiments of Michal describes *either* a stent or a catheter having a coating, but

nowhere are these two embodiments combined together, and there is no motivation for such a combination. As such, Michal does not disclose an implant coating on the inner surface of the stent that interfaces with the delivery device or an adhesion resistant treatment on the outer surface of the delivery device that is in physical communication with the implant.

For example, Michal describes and illustrates a first embodiment of a catheter 11 having a balloon 13 with a coating 18 on the outer surface (See Figure 1 and col. 6, lines 34-42). In a different embodiment, Michal describes and illustrates a stent on a catheter. In this embodiment, only the stent 30 is described and illustrated as having a coating 18 (See Figures 8 and 10-12 and col. 12, lines 8-23). Thus, when a stent and a catheter are described in combination, Michal specifically does not disclose a coating on both the stent and a coating on the catheter. This supports Applicants' position that Michal is only directed to a lubricious, therapeutic coating on any single intracorporeal medical device (whether a stent or a catheter) and does not disclose any relationship between coatings on two different interfacing medical devices—which is what the present claims are directed to. Thus, Michal does not disclose an adhesion resistant treatment on the surface of the delivery device that interfaces with the implant. The Examiner cannot simply pick and choose between embodiments of a reference and combine them if there is no motivation or suggestion to do so. Furthermore, if Michal intended to have a coating on both the stent and the catheter, it would be shown in the embodiment of Figure 8 and 10-12. Thus, the lack of such a disclosure teaches away from this combination.

Although it may be known to use a lubricious coating on a catheter for ease of insertion into a body lumen, as described by Michal, there is no disclosure or teaching of a catheter having an outer surface coated when this surface is covered by a stent. In fact, if a stent were placed on a catheter for insertion, a lubricious coating on the outer surface of the catheter for ease of insertion into the body lumen would be superfluous, since the catheter would be covered by the stent. The outer surface of the stent may have a lubricious or therapeutic coating, but there would be no motivation to also coat the outer surface of the catheter, since it would no longer be in contact with the body lumen.

The Examiner states that the motivation for combining Michal and Savin is "in order to deliver therapeutic and pharmaceutical agents to a targeted area to inhibit or prevent restenosis." Although this may provide motivation for providing a therapeutic on the outer surface of the

stent that interfaces with the body lumen, this would still not provide motivation for providing an implant coating on the inner surface of the stent that interfaces with the delivery balloon. Additionally, neither Savin or Michal disclose an adhesion resistant treatment on the outer surface of the delivery device that is in physical communication with the implant.

The present invention coats the area of the catheter that is in contact the stent in order to prevent stripping the stent coating when the stent is removed from the catheter and implanted in the body lumen. Such a problem was not even contemplated by Michal. Michal is directed to a wholly distinct issue of creating a lubricious or therapeutic coating that allegedly strongly adheres to the device. Thus, the combination of Michal and Savin does not disclose all of the limitations of claim 1 (and all claims that depend therefrom).

Claims 5, 6 and 8-10 are rejected under 35 USC 103(a) for being allegedly rendered obvious by Savin in view of Michal and further in view of U.S. Patent 5,902,631 to Wang et al. ("Wang"). For the reasons discussed above, Michal and Savin do not disclose all of the limitations of claim 1, and all claims that depend therefrom. Wang does not cure these deficiencies. Wang describes a balloon catheter that has a portion with a lubricity gradient. However, the catheter is lubricious to allow movement within the lumen of the body, not to allow for release of a removable implant placed on the outer surface. In fact, Wang does not disclose any such removable implant, let alone an implant with a coating, wherein the adhesion resistant treatment prevents the coating from being stripped from the implant. Thus, the combination of Michal, Savin, and Wang does not disclose all the limitations of claim 1, and all claims which depend therefrom.

Response to Applicant's Previously Asserted Arguments

The Examiner's arguments are not understood and clarification is respectfully requested. The Examiner states that "nowhere in the prior art discloses that the implant adhesion-resistant treatment is capable of removing the implant coating from the implant surface" (Office Action, page 2). It is not understood what the Examiner means. The implant adhesion-resistant treatment of the present invention prevents the implant coating from being stripped from an implant surface, as recited in claim 1. The prior art does not disclose such an adhesion resistant

treatment. Such a treatment is to prevent removal of the implant coating, so it is not understood why the Examiner is stating that the prior art does not say that it can remove the coating. The problem of stripping was not previously appreciated, thus there was no need to provide such a treatment to prevent stripping. Just because the prior art does not say that the coating was stripped does not mean that it was not stripped.

The Examiner also states that "it is an inherent characteristic of coating implants of being stripped from the coating by the blood vessel fluid of the patients during a period of time in order to treat a specific region instead of being stripped off by an adhesion resistant treatment" (Office Action, page 2). It appears that the Examiner is mischaracterizing how the coating is stripped from the device. Once an implant is placed within a body lumen, such as a blood vessel, the coating slowly degrades and disperses into the bloodstream and surrounding tissue. There is no "stripping" of the coating when it is placed in the body lumen. Claim 1 has nothing to do with this process of degradation, but rather is concerned with the delivery process. When the implant is delivered to the target site, the present invention according to claim 1 prevents the coating from being stripped from the implant. If the implant coating was stripped during delivery, this would result in less therapeutic being applied to the target site. Previous delivery devices did not provide any mechanism to prevent this stripping problem.

The Examiner further states that "it will not be efficient for a stent to be stripped of the coating by the implant resistant treatment" (Office Action, page 2). The Examiner is using hindsight reasoning to reconstruct the Applicants' own invention. The Applicants recognized this problem of stripping and thus developed an implant adhesion resistant treatment to solve this problem. Simply because the prior art does not provide an efficient method, does not provide motivation for creating the Applicant's invention.

Regarding Savin, the Examiner states that "col 4, lines 55-57 clearly disclose that the lubricating solution is between the balloon and the sleeve, therefore the lubricating solution is between the balloon and the stent (see Fig. 1)" (Office Action, page 2). This statement does not make sense. In Figure 1, the sleeves 18 and 20 each overlap the balloon 14 for a certain distance and then overlap the stent 16 for a distance D. Since the reference only states that the lubricating solution is provided between the balloon and the sleeves, there is no disclosure that there is lubricating solution between the sleeves 18 and 20 and stent 16 in the region D. The sleeves are

not part of the stent. Furthermore, even if the lubricating solution continued along the entire inner surface of the sleeves, which it does not, this coating would only be between the outer surface of the stent 16 and sleeves 18, 20 and there would still be no coating between the inner surface of the stent 16 and the balloon 14. Thus, Savin does not disclose at least this limitation of claim 1.

CONCLUSION

It is respectfully submitted that the present application is now in condition for allowance, which action is respectfully requested. The Examiner is invited to contact Applicants' representative to discuss any issue that would expedite allowance of the subject application.

Any fees for extension(s) of time or additional fees required in connection with the filing of this response, are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is authorized to charge any such required fees or to credit any overpayment to Kenyon & Kenyon's Deposit Account No. 11-0600.

Respectfully submitted,
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